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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,049	05/22/2001	Sue J. Kenwrick	HO-P01961US1	8342

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EXAMINER
WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
1632	12

DATE MAILED: 09/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,049	KENWRICK ET AL.	
	Examiner	Art Unit	
	Anne M Wehbé	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8 and 32-43, drawn to methods of detecting alterations in the nucleic acids sequence of SEQ ID NO:1, classified in class 435, subclass 6.

II. Claims 9-13 and 44, drawn to methods of detecting alterations in the amino acid sequence of SEQ ID NO:2, classified in class 435, subclass 7.1.

III. Claims 14-15, 18-19, 20, 22-25, drawn to methods of treating disease using a nucleic acid, classified in class 514, subclass 44.

IV. Claims 16-19, 21, 22-25, drawn to methods of treating disease using a protein, classified in class 514, subclass 2.

V. Claims 26-29, drawn to methods of screening a test compound, classified in class 435, subclass 4.

VI. Claims 30, and 45-48, drawn to nucleic acids and kits comprising one or two nucleic acids, classified in class 536, subclass 22.1 or 23.1.

VII. Claims 31 and 49, drawn to amino acids sequences, classified in class 530, subclass 300 or 350.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I-VII are distinct each form the other in that amino acids, i.e. proteins or peptides, and nucleic acids are substantially different in terms of structural, chemical, physical, and biological properties, are made using substantially different techniques and can be used for

substantially different purposes. It is particularly noted that the nucleic acid in not required for the production of the peptide or protein as amino acid sequences can be chemically synthesized or purified from cells. Further, it is noted that nucleic acids and proteins have substantially different modes of activity both in vitro and in vivo and have substantially different requirements in terms of reagents and conditions for their use in *in vitro* assays or for therapeutic purposes *in vivo*.

2. The nucleic acids of invention VI and methods of using the nucleic acids of inventions I, III, and V are related as product and process of use. The inventions can be shown to be distinct if **either** or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids products can be used in numerous materially different process such as those claimed, i.e. the treatment of disease *in vivo*, methods of detecting mutations *in vivo* or *in vitro*. As such, it is clear that the claimed nucleic acids are separately patentable from their various methods of use.

3. The amino acids of invention VII and method of using the amino acid of inventions II are related as product and process of use. The inventions can be shown to be distinct if **either** or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the amino acid products can be used in numerous materially different process than the treatment of

disease, such as the use of the proteins and peptides in *in vitro* binding assays. As such, it is clear that the claimed amino acids are separately patentable from their various methods of use.

4. The amino acids of invention VII and the methods of detecting in an animal mutations in an amino acid sequence of invention IV are patentably distinct in that the amino acids of invention VII are not required for the screening methods and further that the screening methods utilize antibodies and other reagents which are unrelated in structure and function to the amino acids of invention VII.

5. In addition, the methods of invention I-V are separately patentable in that each method utilizes different reagents, and/or operates under substantially different conditions each from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, different classification, and different search requirements, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

If applicant elects the subject matter of groups I, applicant is further required under 35 U.S.C. 121 to elect a first disclosed polynucleotide sequence from the polynucleotide sequences set forth as SEQ ID NOS 4-75 and a second polynucleotide sequence set forth as SEQ ID NOS 4-77 for prosecution on the merits. If applicant elects the subject matter of group VI, applicant is

further required under 35 U.S.C. 121 to elect a nucleic acid sequence from the sequences set forth as SEQ ID NOS: 1, and 4-77. In addition, if application chooses an sequence **other than** SEQ ID NO:1, applicant must elect a second nucleic acid sequence from the sequences set forth as SEQ ID NOS:4-77 for prosecution on the merits.

This is not an election of species. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries

should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER